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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,935	03/06/2002	Adi Shefer	4686-110 US	7056

7590 05/17/2006

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,935	SHEFER ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/21/2006.

Claims 2, 3, 6, 34, 37, and 43-46 have been canceled.

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are pending and included in the prosecution.

(A) The following rejections have been overcome by virtue of applicants' amendments and remarks:

(1) The rejection of claims 1, 4, 5, 7-33, 38-41, and 47 under 35 U.S.C. 112, second paragraph, as being indefinite.

(2) The rejection of claims 1, 4, 5, 9, 11-18, 20, 21, 26, 27, 29, 30, 32, 38, 42, and 47 under 35 U.S.C. 102(e) as being anticipated by US 2003/0107149 ('149) because the film disclosed to be used for cosmetic has a substrate.

(3) The rejection of claims 33, 35, and 36 under 35 U.S.C. 102(a) and (e) as being anticipated by US 2001/0007671 ('671) because of the new limitations added to the claims.

(4) The rejection of claims 33, 35 and 36 under 35 U.S.C. 102(e) as being anticipated by US 6,419,935 ('935) because of the new limitations added to the claims.

(B) The following rejection has been discussed in the previous office action and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, 5, 7, 8, 10, 13-18, 20, 21, 27, 29, 30, 32, 35, 36, 38-42 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0027833 ('833), with the effective filing date of May 07, 2001.

US '833 discloses pharmaceutical composition in the form of single adhesive polymeric layer, film or matrix that deliver local anesthetic agent to the skin (abstract; page 2, paragraphs 0014-0017; page 9, paragraph 0091). The polymeric layer is water-soluble and can be removed easily by application of water, and selected from PVP, PVA, hydroxypropyl cellulose, starch and starch derivatives with a pharmaceutically active agent homogenously admixed therein with a permeation enhancer (page 2, paragraphs 0021, 0023; page 6, paragraph 0070, 71; page 7, paragraphs 0077, 0078). The polymeric layer further comprising bactericidal agent selected from iodine, silver,

mercury compounds, phenol and chlorhexidine (page 4, paragraph 0051); antibiotic including tetracycline (page 4, paragraph 0052); capsaicin, and peptide or proteins (page 4, paragraphs 0053, 0055); mineral oils (page 7, paragraph 0074); excipients including colorant (therefore the patch is colored), plasticizer, antioxidants, pH regulators, menthol and glycerol (page 6, paragraph 0064; page 8, paragraph 0083-0087). Part of the active agent could be encapsulated within liposomes (page 5, paragraph 0060). The active agent is delivered within 10 minutes and lasts up to 6 hours (page 2, paragraph 0026). The polymeric film has thickness of 0.01 mm to 2 mm (page 7, paragraph 0076).

Response to Arguments

3. Applicant's arguments filed 02/21/2006 have been fully considered but they are not persuasive.

Applicants traverse this rejection by arguing that:

- US '833 teaches liquid composition including monohydric alcohol which only when applied to the skin forms film, while the present invention is solid film.

In response to this argument, the examiner is pointing out to the scope of the present claim that is drawn to single polymeric layer formed of water-soluble film forming polymer. The formation of the film when applied to skin or before application to the skin is not part of the claim limitation. The reference disclosed film forming water-soluble hydrophilic polymers that form water-soluble film (paragraph 0078) with the preferred polymers are polyvinyl pyrrolidone (PVP), starches, and hydroxypropyl cellulose, which are all claimed by applicants. The claims' language permits the

presence of monohydric alcohol, and does not exclude other ingredients that are water-soluble. The present claims do not recite solid film. The same polymers will inherently form film with the same properties such as adhesiveness and tackiness.

- Applicants argue that US '833 discloses composite comprising backing film. US '833 teaches an embodiment without backing layer that may include hydrophobic layer, which may not dissolve by rinsing with water. The present invention is single polymeric layer.

In response to this argument, applicants' attention is drawn to the teaching of the reference on paragraph 0023 regarding the backing: "optional", "if present". On paragraph 0091 the reference disclosed "single layer that serves as drug reservoir and bioadhesive material", i.e. no additional adhesive layer. The reference disclosed on paragraph 0077 regarding the polymer film layer: "A water soluble film can be removed easily with application of water". On paragraph 0078, the reference disclosed "hydrophilic polymers form water soluble film". Therefore US '833 disclosed single water-soluble polymeric film removed by dissolving in water and adheres to the skin without additional adhesive, as instantly claimed.

- Applicants argue that US '833 teaches pressure sensitive adhesive, while the present invention tacky by itself and adheres to the skin without adhesive.

In response to this argument, the examiner is pointing out to paragraph 0091 on page 9 where the reference disclosed "single layer that serves as drug reservoir and

bioadhesive material". Regarding the polymer becoming tacky upon wetting the skin, it is an inherent property to a specific polymer.

- Applicants argue that US '833 does not teach the active ingredients are encapsulated in nano-spheres or micro-spheres as claimed in claim 16.

In response to this argument, the examiner is pointing out to the end of paragraph 0060 on page 5 where US '833 disclosed the active agent encapsulated in liposomes. Liposomes are spherical and according to their size they can form nano-spheres or micro-spheres, and applicants not claiming any specific sizes, therefore, liposomes disclosed by US '833 read on the claimed micro-spheres and nano-spheres. Attached is text from "LIPOSOMES AS TOOLS IN BASIC INDUSTRY" to show that liposomes are vesicles of different sizes.

(C) The following new ground of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 9, 11, 12, 19, 22-26, 31, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '833 in view of US 2001/0007671 ('671).

The teachings of US '833 are discussed above.

However US '833 does not teach the salicylic acid as claimed in claim 9, ibuprofen as in claim 11, the anti-irritant claimed in claim 12, the transparent polymeric layer as claimed in claim 19, the cosmetics claimed in claims 22-25, the effervescent claimed in claim 26, wetting the film before application to the skin as claimed in claims 31, 33, 35, and 36, or the period of applying the patch as claimed in claim 36.

US '671 teaches a cosmetic, pharmaceutical, or dermatological patch for application of active agent to the skin (abstract; page 1, 0012, 0015). Skin can pre-wetted prior to application of the patch (page 1, 0014). The patch imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin (page 1, paragraph 0007). The patch includes a water-polymer

matrix layer comprising an active agent and polymer including hydroxypropyl cellulose (Figures 1; page 2, 0017, 0018, 0024, 0035; page 3, 0046; page 7, claim 15; page 8, claims 67-70). The active agents include anti-oxidants, free-radical scavengers, moisturizers, bleaching agents (depigmentation agents), liporegulators, anti-acne agents, anti-aging agents, anti-wrinkle agents, anti-inflammatory agents, softeners, keratolytic agents, anti-bacterials, anti-fungal, antiperspirants, deodorants, skin conditioners, immunomodulators, nourishing agents, moisture absorbers and sebum absorbers (page 3, 0046, 0047). The patch is transparent or colored (page 2, 0020; page 3, 0050). The composition includes acetylsalicylic acid (aspirin) (page 3, 0047). The composition comprises sodium carbonate and sodium bicarbonate (page 3, 0043). The patch is applied to the skin from about few seconds to about few days (page 1, 0015). The composition also comprises mineral oils (page 2, 0038). The composition further comprises salicylic acid which is a keratolytic agents (page 3, 0048; page 8, claim 60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '833 and select the active agent suitable for delivery to the skin or across the skin according to the specific condition to be treated, and made the patch to be transparent and wet the skin before its application as disclosed by US '671, motivated by the teaching of US '671 that wetting the skin before patch application imparts great softness, freshness and coolness and easy manipulation during application and removal from the skin, with reasonable expectation of delivering wide

varieties of beneficial active agent to the skin from transparent easily manipulated patch during application and removal from the skin.

Response to Arguments

7. Applicant's arguments filed 02/21/2006 have been fully considered but they are not persuasive. Applicants traverse the combination of US '833 and US '671 by arguing that US '671 does not teach patch that dissolve and removed by water and formed of single polymeric layer and it teaches gellan gum that does not dissolve in water.

In response to this argument, the examiner is pointing out to the new ground of rejection necessitated by applicants' amendment, wherein US '671 is relied upon for the solely teaching of some active ingredients that are suitable for transdermal and topical delivery and also to show that patch can be transparent especially if it is made from the same polymers used by applicants. Further, US '671 is relied upon for teaching wetting of the skin before applying the polymeric patch to the skin for easier manipulation during application and removal. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Claims 9, 11, 12, 22-26, 28, 31, 33, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '833 in view of US 6,419,935 ('935).

The teachings of US '833 are discussed above.

However US '833 does not teach the salicylic acid as claimed in claim 9, ibuprofen as in claim 11, the anti-irritant claimed in claim 12, the cosmetics claimed in claims 22-25, the effervescent claimed in claim 26, size and shape of the patch, wetting the film before application to the skin as claimed in claims 31, 33, 35, and 36, or the period of applying the patch as claimed in claim 36.

US '935 disclosed cosmetic skin treatment method includes providing a patch with good adhesiveness without drying the skin that includes polymeric matrix that includes at least one cosmetically active compound (abstract; col.1, lines 43-57; col.2, lines 49-57; col.9, lines 66-67). The patch is configured to adhere to the dry skin and to the moistened skin to provide treatment and cleansing the skin (abstract; col.2, lines 1-3, 57-59; col.3, lines 12-14). The patch provides treatment for time ranging from 5 minutes to 60 minutes (col.2, lines 8-12; col.4, lines 64-67). The polymeric matrix includes polyvinyl alcohol, starches, cellulose derivatives, which are inherently bioadhesive, water-soluble and film forming polymers (col.6, lines 1-6; col.7, lines 1-12). The cosmetically active compounds to be incorporated in the matrix include moisturizers, keratolytic agents, anti-wrinkle agents, self tanning agents, bleaching agents and lightening agents (depigmentation agents), antioxidants, free-radical scavengers, liporegulators, anti-acne agents, anti-aging agents, anti-inflammatory agents, steroidal anti-inflammatory agents, refreshing agents, antibacterials, antifungals, and nourishing agents (col.4, lines 23-34; col.5, line 36). Antibacterials disclosed by the reference include tetracyclines, erythromycin, and clindamycin (col.5, lines 3-4). The keratolytic agents include salicylic acid (col.4, line 61 till col.5, line 1). The active

compounds include acetylsalicylic acid (aspirin) (col.5, lines 20-21). The reference disclosed tanning agents include dihydroxyacetone (col.5, lines 62-65). The patches are cut to shapes designed to fit on various parts of the body and the preferred size ranges from 1 cm^2 to 30 cm^2 (col.9, lines 6-18). The polymeric matrix forms a layer having a thickness of 0.2 mm (col.9, lines 66-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '833 and select the active agent suitable for delivery to the skin or across the skin according to the condition to be treated, and select the patch to be with the specific size according to the site of application, and wet the skin before its application as disclosed by US '935, motivated by the teaching of US '935 that the disclosed patch and its method of use provides good adhesiveness without drying the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from dissolvable film that has good adhesiveness without causing drying of the skin.

Response to Arguments

9. Applicant's arguments filed 02/21/2006 have been fully considered but they are not persuasive. Applicants traverse the combination of US '833 and US '935 by arguing that US '935 swell in response to moisture and does not dissolve.

In response to this argument, the examiner is pointing out to the new ground of rejection necessitated by applicants' amendment, wherein US '935 is relied upon for the solely teaching of some active ingredients that are suitable for transdermal and topical

delivery and also to show that patch can be transparent especially if it is made from the same polymers used by applicants. Further, US '935 is relied upon for teaching wetting of the skin before applying the polymeric patch to the skin for easier manipulation during application and removal. Further US '935 teaches the size of the patch as claimed as well as shapes that shapes designed to fit on various parts of the body. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

10. Claims 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '833.

The teaching of US '833 are discussed above.

However, the reference does not teach the size of the patch.

It would have been obvious to one having ordinary skill in the ad at the time the invention was made to have a polymer film or patch with a size between 1 cm^2 to 30 cm^2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Response to Arguments

11. Applicant's arguments filed 02/21/2006 have been fully considered but they are not persuasive. Applicants repeat the same argument against US '833, therefore, the examiner's response is hereby repeated as in section 3 of this office action.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali